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EXAMINER

LIEU, JULIE BICHNGOC

ART UNIT	PAPER NUMBER
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2636

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,294

Applicant(s)

STRODA ET AL.

Examiner

Julie Lieu

Art Unit

2636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-27, 29 and 31 is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-23 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 2636

DETAILED ACTION

1. This Office action is in response to amendment filed July 28, 03. Claim 31 has been amended. Claim 30 has been canceled.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to originally disclose preventing the step of arming the pressure pad when the step of removing the pressure above the predetermined pressure are separated in time by more than a preset period of time nor preventing the step of activating an alarm when the

Art Unit: 2636

step of applying pressure above the predetermined pressure are separated in time by more than a preset period of time.

Claim Rejections - 35 USC § 102

4. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boon (US Patent No. 5,796,059).

Claim 11:

Boon discloses a system for monitoring a patient, comprising:

- a. A pressure pad for providing a signal indicating a pressure condition;
- b. A control housing connected to the pressure pad and responsive to the signal; and
- c. A casing 52 at least partly encasing the pressure pad.

Claim 12:

The pressure pad in Boon is activated by removal of pressure and inactivated by application of pressure.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 2636

6. Claims 7-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Stroda (US Patent No. 6,166,644).

Claim 7:

Stroda discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad under the patient that activates a first switch when energized (figs. 4 and 5)
- b. attaching a fastener (fig. 4) to the patient, wherein if the patient moves beyond a predetermined distance, a second switch moves between one of an open state of a closed state to the other of the open and closed state
- c. providing an alarm signal when either the first or second switch is activated wherein the pressure pad is activated by removal of pressure and reset by application or pressure.

Claim 8:

The fastener is attached to the clothing of the patient. Fig. 4.

Claim 9:

Stroda's system provide verbal message to the patient (fig. 7).

Claim 10:

Stroda transmits a signal to a remote station and providing an alarm to a caretaker at the remote station. See fig. 6.

Claim Rejections - 35 USC § 103

7. Claims 1, 3, 6, 13-15, and 26-27 are rejected under 35 U.S.C. 102(3) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Stroda (US Patent No. 6,166,644).

Claim 1:

Boon discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;
- b. energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);
- c. applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)
- d. arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;
- e. activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad
- f. disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time

Art Unit: 2636

more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays, such as that in Stroda (timer 158), because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

Regarding the claimed disposing the pad when patient no longer has use of the pressure pad without permitting use by another patient, it would have been obvious to one skilled in the art that this is up to the implementer and/or user to decide whether the pad should be a disposable pad and would be discarded after each use of a patient for sanitary purposes.

Claim 3:

Though not clearly stated, it would be inherent that an alarm is provided to a caretaker.

Claims 4 and 5:

It is not clear in Boon where exactly the alarm is located. However, it would have been obvious to one skilled in the art to recognize positioning the alarm at locations because it would be convenient for monitoring staff to be alerted of the situations.

Claim 6:

Art Unit: 2636

The cover 52 of the pressure pad in Boon is plastic, however, it is not disposable. Nonetheless, the concept making a cover of something disposable in order to achieve clinical sanitary and safety to prevent spread of disease is conventional in the art. For example, disposable bedspread, pillow case, etc... Therefore, it would have been obvious to one of ordinary skill in the art to make the cover in Boon to be disposable as desired so that the device can be place directly beneath the patient.

Claim 13:

Boon fails to disclose a recorded voice message sounding within hearing distance of the patient. Nonetheless, such feature is conventional in the art as taught in Stroda wherein the voice alarm is located near the station. In light of this teaching it would have been obvious to one skilled in the art to provide a verbal warning device within the hearing distance of the system in Boon for the same purpose as in Stroda.

Claim 14:

In Boon, the pressure pad responds to pressure by reducing electrical resistance between a first point and a second point. The apparatus including a switch armed upon the reduction of electrical resistance and an alarm for providing the alarm when the switch has been armed and the electrical resistance is under a predetermined resistance threshold, wherein a movement of the patient from the pressure pad triggers the alarm. Col. 3, third paragraph to col. 4, first paragraph.

A time delay, such as 1 second, is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art. Therefore, it would have been obvious to

Art Unit: 2636

one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

Claim 15:

The alarm in Boon provides the alarm when the switch has been armed and electrical resistance is under the predetermined resistance threshold. Regarding the time delay between 2 seconds and 3 seconds in duration, it is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

Claim 23:

Boon discloses a method of monitoring a patient, comprising the steps of:

- a. placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;
- b. energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);
- c. applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)
- d. arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;

- e. activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad
- f. disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed activating the alarm when the pressure has been on the pad for more than a predetermined time and is removed from the armed pressure pad after the predetermined time, it would have been obvious to one skilled in the art to consider some time delays, such as that in Stroda (timer 158), because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a sensor placed in juxtaposition 30, 32 with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position or intended movement of the patient.

Art Unit: 2636

7. Claims 17-20 are rejected under 35 U.S.C. 102(3) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Smith, III (US Patent No. 3,737,930).

Claim 17:

Boon disclose an a pressure pad comprising an alarm system having a pressure switch 12,14, the alarm being connected to the switch, and being armed upon the pressure being placed on the pressure pad and activated upon a release of pressure of the pressure removed. Boon fails to disclose a gel cushion. Nonetheless, the use of gel cushion to provide resting comfort to patient is conventional in the art as shown in Smith, III. Therefore, it would have been obvious to one skilled to use a gel cushion with the system in Boon, by placing it on top of the pressure sensing device in Boon because it provides comfort while pressure on the gel cushion would result in pressure on the pressure switch.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when health personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off.

Claims 18 and 19:

Art Unit: 2636

Different forms of alarm indication such as visible or audible would not constitute an inventive step but a choice in design because they are functionally equivalent in providing an alert signal to a user.

Claim 20:

In Boon, the pressure switch includes two conductors spaced by a flexible material that permits contact between the conductors under a predetermined amount of pressure.

8.

8. Claims 2, 21-23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Stroda (US Patent No. 6,166,644) and Triplett et al. (US Patent No. 4,175,263).

Claims 2, 21, and 22:

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position.

Art Unit: 2636

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Triplett et al. (US Patent No. 4,175,263).

Claim 28:

Boon discloses a system for monitoring a patient, comprising:

- a. a pressure pad for providing a signal indicating a pressure condition;
- b. a control housing connected to the pressure pad and responsive to the signal; and
- c. a casing 52 at least partly encasing the pressure pad.

Boon fails to disclose a second sensor. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station is activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position or intended movement of the patient.

Allowable Subject Matter

10. Claims 24-27, 29, and 31 are allowed.

Remarks

10. Applicant's arguments filed 7/28/03 have been fully considered but they are not persuasive.

Argument 1:

The applicant has argued that claim 11 recites “a casing at least partly encasing the control housing and the pressure pad” while Boon does not disclose such casing. The applicant has pointed out that in fig. 3 a control unit and the casing are shown at 10 with the two being interconnected by the cable 40.

Argument 2:

The applicant has submitted that claim 7 recites “placing a pressure pad under the patient that activates a first switch when energized” and contended that Cross does not disclose this.

Argument 3:

The applicant has stated that the examiner had provided no support for the allegations that it would be obvious to a person of ordinary skill in the art to dispose of the pad after use or to tear the plastic after use so it could not be used again or to cause the alarm to be provided only upon the release of pressure after the pressure has been applied continuously for a period time. The applicant has further asserted that it is not obvious to provide single use of the pad because it costs money and it is not obvious that it would be necessary to take a step such as tearing the

Art Unit: 2636

plastic when the patient is released or that there is any need for circuitry that will prevent the alarm from being given upon the initial pressure being applied to the pad. The applicant also has stated why would a person know that the alarm should not be given unless the patient has been on the pressure pad for a predetermined period of time rather than providing an alarm every time that the patient leaves the pad.

Argument 4:

With regards to claims 17-20 the applicant has contended that it is not obvious to a person of ordinary skill in the art to reject two parts of a combination merely on the ground that those two parts exist in the prior art.

Argument 5:

The applicant has argued claims 4 and 5 but using limitation of claim 1 and has stated that the examiner fails to establish prima facie.

Argument 6:

With respect to claims 23 and 28, the applicant has asserted that neither Triplett nor Boon disclose these features and stated that there must be some logical reason based on fact causing to be unobvious and no such reason has been given by the examiner.

Argument 7:

Art Unit: 2636

Regarding claim 13, the applicant has again asserted that the prima facie case is not established.

Response to Applicant's Remarks

Response to argument 1:

It is submitted that casing encases the pressure pad, i.e. at least partly encases the pressure pad and the control housing.

Response to argument 2:

The applicant has submitted that claim 7 recites "placing a pressure pad under the patient that activates a first switch when energized" and contended that Cross does not disclose this.

Response to argument 3:

The examiner again submits that it is up to the implementer to dispose of the pad after use as desired. The use of a cover on a protected article against unsanitary is very conventional.

If it is not obvious to dispose of the pad after a single use because it is costly then why the applicant does that? If the applicant can dispose of the pad regardless of its cost why can't others do the same?

Regarding the argument that there is no need for circuitry to prevent the alarm from being given upon the initial pressure being applied to the pad, it is submitted that the use of time delay

Art Unit: 2636

is old and conventional in the art in alarm circuit to prevent false, annoying alarms. Refer to the attach Stroda

Response to argument 4:

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969. In this case, the gel cushion in Smith, III provides comfort to a patient when placed on the pressure pad. This is similar to the use of a Dr. Scholls gel cushion inside a person's shoes to provide comfort to a person's foot, which is a general knowledge available to a very ordinary person.

Response to argument 5:

It appears that the applicant has intended to argue claims 4 and 5 depend on claim 1 which the applicant believes patentable so these claim should be patentable, thus no response is deemed necessary.

Response to argument 6:

Art Unit: 2636

The examiner submits that the reasons stated in the rejection are logical reasons.

Response to argument 7:

It is submitted that any ordinary person would know that the verbal warning device must be placed within the hearing distance, otherwise it would not be heard.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Lieu whose telephone number is 703-308-6738. The examiner can normally be reached on Mon-Thursday, 9:00am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Hofsass can be reached on 703-305-4717. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.



Julie Lieu
Primary Examiner
Art Unit 2636

jl
October 15, 2003